K113276

C-RAD

FEB 2 7 2012

510(k) SUMMARY

Owner

C-RAD Positioning AB
Bredgränd 18
753 20 Uppsala
Phone no: +46 18 666930
Fax no: +46 18 126930

Contact person

Janina Östling
Quality Manager
Phone no: +46 18 666940

Date of preparation

October 25, 2011

Trade name of device

Catalyst

Common name

Radiotherapy positioning system

Classification name

Medical charged-particle radiation therapy system
Regulation: 21 CFR 892.5050

Predicate marketed devices

Sentinel (K082582) – C-RAD Positioning AB
GateCT-RT (K072171) – Vision RT Ltd.

Device description

The Catalyst system is a further development of the Sentinel system and is using the same software platform but contains a new hardware device which enables overall higher performance and the possibility to run multiple applications in parallel.

Catalyst is an advanced system based on optical surface tracking for patient monitoring during the radiotherapy treatment process. The Catalyst platform is based on advanced structured light measurements with multipurpose software modules covering different tasks in the treatment procedure. The c4D multi-application software supports all modes of operation in one integrated package. The software is user friendly and requires a minimum of user interaction in the daily clinical workflow, while providing the advanced user with sophisticated data management, analysis and reporting functionalities. The software is designed to integrate with existing systems at the clinic, such as CT, linacs and R&V systems, and with motorized couch tops.

Catalyst includes three application modules, cPosition for fast and accuracy patient positioning, cMotion for motion detection during the treatment delivery procedure, and cRespiration for detecting respiratory motion and generating a gating signal for synchronized imaging or gated treatment delivery.

The Catalyst hardware consists of a single scanner unit containing the projector and camera, mounted in the ceiling in front of the gantry. The scanner is connected to the PC running the c4D software.

During patient surface acquisition, a sequence of structured light patterns is illuminating the patient while the camera records a number of images. From the data acquired, a complete 3D surface of the patient can be reconstructed using the principles of optical triangulation. Information from the system is shown on a PC monitor in the treatment room as well as the control area. The system can also project a high resolution multi-color light field onto the patient surface, thus avoiding the need for the personnel to look at the PC monitor when setting up the patient. The system optionally records data which can be used for further analysis of actual patient motion during each treatment session.

cPosition

Once the treatment planning has been performed, the resulting plan can be transferred to the Catalyst system through import from the industry-standard DICOM format, creating the reference data necessary for patient positioning. Reference data can also be by created using the Catalyst scanner. In the treatment room, synchronization with the LINAC or R & V (Record and Verify) system ensures that the correct reference data is called up automatically when the patient is selected for treatment, and also eliminates the need for any manual selection of the patient in the Catalyst system.

By advanced surface registration algorithms the actual patient position is compared to the predefined reference, suggesting within seconds a correction in six degrees of freedom of the patient's position. With interface to major accelerator vendors the suggested patient position is transferred to the respective couch control system and fast and accurate alignment is achieved. Suggested corrections are also projected directly onto the patient's skin to further simplify the set-up process.

cMotion
cMotion monitors the movement of the patient during treatment delivery and warns if the patient moves outside the allowed tolerances. A beam hold signal is also produced by the system, which enables automatic interruption of the treatment delivery in case of large detected patient motion.

cRespiration
In the treatment room, the patient's respiratory motion is monitored and the treatment beam will be turned on only when the signal is within a predetermined gating window. An imaging system can be triggered so that image acquisition is synchronized to the same gating window. Alternatively, so-called 4D reconstruction is possible by providing the recorded respiratory signal for retrospective gating of the acquired images.

Intended use

The Catalyst system is intended for use in radiation therapy clinics to accurately set-up and position patients in a reproducible way prior to treatment, and to monitor the patient continuously during treatment. The system provides information about a patient's position and the adjustments required in order to position the patient as close as possible to a reference setup. During monitoring, the system reports deviations in the patient's position during treatment and disables the treatment beam in case of large detected movements. The system can also track the patient's respiratory motion for supporting synchronized image acquisition or gated treatment delivery.

The system shall only be used by hospital personnel, qualified to work in radiation therapy or diagnostic imaging departments.

Technological comparison

The difference between the Catalyst system and the Sentinel and GateCT-RT systems is mainly in the technology used for image acquisition, but would not affect safety or effectiveness.

The Catalyst system uses a structured light projector/camera system to acquire a set of 3D contours that represents the patient surface, while the Sentinel uses a laser camera and the GateCT-RT system instead uses a fixed projected light pattern and two cameras. All three systems use a triangulation technique to calculate the 3D positions from the acquired 2D images.

Since the Catalyst system and its predicate devices all perform with the same measurement accuracy, and Catalyst has the same functionality as the Sentinel system for patient positioning and monitoring, and the same functionality for the GateCT-RT system for interrupting the treatment beam and synchronized imaging, no new safety concerns are raised.

The submitted verification and validation documentation demonstrates that the Catalyst is suitable for its intended use and is safe to use.

Device comparison table

	C-RAD Catalyst (K113276)	C-RAD Sentinel (K082582)	VisionRT GateCT-RT (K072171)
Intended use	The Catalyst system is intended for use in radiation therapy clinics to accurately set-up and position patients in a reproducible way prior to treatment, and to monitor the patient continuously during treatment. The system provides information about a patient's position and the adjustments required in order to position the patient as close as possible to a reference setup. During monitoring, the system reports deviations in the patient's position during treatment and disables the treatment beam in case of large detected movements. The system can also track the patient's respiratory motion for supporting synchronized image acquisition or gated treatment delivery. The system shall only be used by hospital personnel, qualified to work in radiation therapy or diagnostic imaging departments.	Identical capabilities except that the Sentinel system cannot interrupt or gate the radiation therapy treatment beam.	Identical capabilities for tracking of respiratory motion, synchronized image acquisition and gated radiation therapy treatment.
Indications for use	*Same as above*	*Same as above*	*Same as above*
Target population	External-beam radiation therapy patients	Identical	Identical
Anatomical sites	No specific restrictions	No specific restrictions	No specific restrictions
Where used	Hospital	Hospital	Hospital
Energy used and/or delivered	Visible light (LED)	Visible light (laser)	Visible light
Human factors	Only qualified and trained personnel are allowed to	Identical	Identical

	run the system. Usability validation tests performed in collaboration with Hospitals.		
Design	Optical triangulation measurement system using structured visible light pattern using one LED light source and one digital camera. Additional LED light sources for projecting visible light patterns.	Optical triangulation measurement system using one line laser and one digital camera.	Optical triangulation measurement system using one light projector and two digital cameras.
Performance	Measurement accuracy better than 1 mm.	Measurement accuracy better than 1 mm.	Measurement accuracy better than 1 mm.
Standards met	EN/IEC 60601-1	EN/IEC 60601-1, EN/IEC 60825	EN/IEC 60601-1
Materials	No hazardous materials used, system not in direct contact with patients.	No hazardous materials used, system not in direct contact with patients.	No hazardous materials used, system not in direct contact with patients.
Biocompatibility	N/A	N/A	N/A
Compatibility with the environment and other devices	EMC according to EN/IEC 60601-1-2	EMC according to EN/IEC 60601-1-2	EMC according to EN/IEC 60601-1-2
Sterility	N/A	N/A	N/A
Electrical safety	EN/IEC 60601-1	EN/IEC 60601-1	EN/IEC 60601-1
Mechanical safety	EN/IEC 60601-1	EN/IEC 60601-1	EN/IEC 60601-1
Chemical safety	N/A	N/A	N/A
Thermal safety	N/A	N/A	N/A
Radiation safety	N/A	N/A	N/A

Performance data

The measurement accuracy is better than 1 mm for Catalyst and its predicates. The performance test results are presented in the application.

Further is an overview of all verification and validation activities presented.

The results from the verification of the Catalyst product shows that all important requirements and safety keys have been implemented and are functioning according to the requirement specification. The verification and validation also shows that all residual risks regarding the identified safety requirement keys listed in are acceptable and the product is safe for use.

The validation performed at Varian Medical Systems, UAS and Malmö shows that the Catalyst application for patient positioning, monitoring and respiratory gating is functioning according to its intended use.

Conclusion

The Catalyst system is substantially equivalent to the predicate devices in terms of their intended use and performance.

Performance data has been submitted to show that Catalyst achieves its intended use, is safe to use and that the technological differences between Catalyst and its predicates raise no new effectiveness or safety concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Janina Östling
QualityManager
C-RAD Positioning AB
Bredgränd 18
753 20 Uppsala
SWEDEN

FEB 2 7 2012

Re: K113276
Trade/Device Name: Catalyst
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: February 16, 2012
Received: February 21, 2012

Dear Ms. Östling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

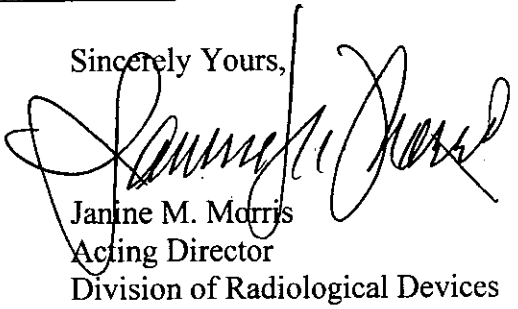
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

C-RAD

INDICATIONS FOR USE

510(k) Number (if known): K113276

Device Name: Catalyst

Indications for use:

The Catalyst system is intended for use in radiation therapy clinics to accurately set-up and position patients in a reproducible way prior to treatment, and to monitor the patient continuously during treatment. The system provides information about a patient's position and the adjustments required in order to position the patient as close as possible to a reference setup. During monitoring, the system reports deviations in the patient's position during treatment and disables the treatment beam in case of large detected movements. The system can also track the patient's respiratory motion for supporting synchronized image acquisition or treatment delivery.

The system shall only be used by hospital personnel, qualified to work in radiation therapy or diagnostic imaging departments.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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